REMARKS

Claims 1-4, 8, 19 and 109 are pending in the application. Claims 5, 6, 9-18, 20-23, 96-108 are withdrawn from consideration. Claims 7 and 24-95 are cancelled.

Reconsideration of the application in view of the current claims and further in view of the following remarks is respectfully requested.

I. DOUBLE PATENTING REJECTION

Claims 1-4, 8 and 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims in US application Nos 11/543,312, 11/690,767 and 11/770,608.

Applicants will address this issue and file a terminal disclaimer should the claims be deemed allowable.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 1-4, 8, 19 and 109 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

Applicants respectfully traverse this rejection. Claims 1-4, 8, 19 and 109 are described in sufficient detail in the specification such that one skilled in the art can reasonably conclude that Applicants had possession of the claimed invention.

As summarized in the MPEP § 2163, "[t]he first paragraph of 35 U.S.C. § 112 requires that the 'specification shall contain a written description of the invention ...' This requirement is separate and distinct from the enablement requirement. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991)". The section goes on to provide that "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." *Id.* Thus, the issue is whether the original application provides adequate support for the claims.

The claims and specification of the instant application do provide ample written description for the pending claims. Claim 1 recites "wherein an elevation in the concentration of said

analyte(s) in the test sample of about two fold relative to the reference concentration is indicative of the presence of severe sepsis in the human". The Examiner alleges in the Office Action (p 4-5) that

> "paragraphs 0011 and 0012 do not make any mention of two fold elevations of any analyte. Paragraph 0145 states that possible markers for sepsis should show a two fold elevation and paragraph 0196 states that MPIF-1 shows a four fold elevation; however, neither of these paragraphs mention diagnosis of severe sepsis and paragraph 0196 states that some analytes were significantly lower in sepsis, which contradicts paragraph 0145. Therefore, the two fold and four fold limitations are new matter.

However, the Examiner has failed to analyze the cited paragraphs in the context of the entire application. It clear throughout the specification that the invention is directed to the diagnosis of sepsis and/or severe sepsis by measuring the biomarkers identified by Applicants in the instant application. For example, paragraphs [0017] and [0018] of the published application disclose methods for diagnosis severe sepsis if the concentration of at least one analyte is elevated relative to a reference sample. These paragraphs described both MPIF-1 and TNF-R1. Paragraphs [0041] – [0055] of the published application show examples of statistical analyses that can be used to identify biomarkers that are significantly different between sepsis samples and reference samples. In addition, the use of an elevation in the concentration of an analyte in a test sample of about two fold relative to the reference concentration as a threshold to identify a biomarker is fully described in Examples 6, and 7, for example, in paragraphs [0145], [0196] and [0204] of the published application. Furthermore, the specification describes studies in which markers, such as MPIF-1 and TNF-R1, are elevated two fold or more in sepsis patients in comparison to control samples (See Examples). Thus, when the specification is considered in its entirety, it is clear that there is ample support for the diagnosis of severe sepsis by comparing the concentration of an analyte(s) to a corresponding reference concentration where an elevation in concentration of the analyte(s) in the test sample of about two fold relative to the reference concentration is indicative of the presence of severe sepsis. Thus, a person of ordinary skill in the art would reasonably conclude that the Applicants had possession of the claimed invention.

The Examiner argues that "paragraph [0196] states that some analytes were significantly lower in sepsis, which contradicts paragraph 0145". This argument is without merit. It is clear

throughout the specification that some biomarkers of severe sepsis are elevated during sepsis while some other markers are depressed (See for example Abstract, and paragraphs [0017], [0018] and [0068]). Claim 1 is directed to the diagnosis of severe sepsis using biomarkers that are elevated during severe sepsis (e.g. MPIF-1). The fact that the concentration of some biomarkers decreases during sepsis does not contradict the fact that the concentration of other biomarkers increases with sepsis and that those increased biomarkers can be used for diagnosis of severe sepsis as claimed in claim 1 and disclosed throughout the specification.

With respect to claim 109, the recitation "wherein an elevation in concentration of MPIF-1 in the test sample of about four fold relative to the reference concentration is indicative of the presence of severe sepsis in said human" is fully described in the specification (See Examples). For example, paragraph [0196] of the specification describes that MPIF-1 levels are elevated four fold in sepsis patients as compared to sick controls.

Therefore, the specification provides ample description in sufficient detail of methods to diagnose severe sepsis as recited in the claims. Giving the explicit description provided by the specification, one skilled in the art would recognize that Applicants had possession of the claimed invention.

Based on the reasons provided above, withdrawal of the rejection under 35 U.S.C. 112, first paragraph, is respectfully requested.

CONCLUSION

Applicants submit that this paper fully addresses the Final Office Dated November 6, 2009, and respectfully requests that the Examiner advance the application to issuance. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned attorney at (650) 849-3211.

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 36671-747.201).

Respectfully submitted,
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